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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,584	03/12/2007	Susan Bortolin	TMB-006	9399

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GOODWIN PROCTER LLP  
PATENT ADMINISTRATOR  
53 STATE STREET  
EXCHANGE PLACE  
BOSTON, MA 02109-2881

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

NOTIFICATION DATE	DELIVERY MODE
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02/08/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/579,584	<b>Applicant(s)</b> BORTOLIN ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 and 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/3/09; 11/09/09</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Applicants are herein informed regarding the change of Examiner of this application.

Applicant's election with traverse of Group I (claims 1-9) in the reply filed on November 03, 2009 is acknowledged. Traversal is on the grounds that there is no lack unity of the invention.

With regard to the lack of unity and election of SEQ ID Nos., Applicants' arguments were fully considered and found unpersuasive. Applicants' argue that the prior art does not teach tagged allele specific primers and assert that the primers sequences taught by the prior art does not anticipate the sensitivity and specificity of the primers. Applicants' arguments were found unpersuasive. First, with regard to the arguments based on sensitivity and specificity of the primers, it is noted that the instant claim 10 recites the kit components comprising sequences of Seq ID Nos that are anticipated by the prior art on the record and the claim 10 as presented do not require the sensitivity and specificity and the sequences do not read on said sensitivity and specificity, therefore the claim 10 lacks the special technical feature that binds different Groups of invention together as stated in the previous office action. Second, the amended claims did not change the scope of the claims since the SEQ ID Nos. as recited in claim 10, were previously present in the amended claims and the broad claim 10 is anticipated by the cited prior art. Third, the issues under 35 USC 112, and 101 are not the same for the two groups. Hence the lack of unity is deemed proper.

***Status***

2. Claim 22 is included and considered for examination herein along with the elected claims 1-9 since the claim 22 is drawn to a method. Claims 1-9 and 22 along with elected SEQ ID Nos. 2, 4,

and 13-16 are considered for examination. Claims 10-13, 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

***Priority***

3. This application filed on March 12, 2007 is a 371 of PCT/CA04/01974 filed on 11/17/04 which claims benefit of 60/520,303 filed on 11/17/03.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuber et al. (WO 01/71028 A2) in view of Pancoska et al. (US 7,608,398).

Reuber et al. teach a method for detecting the presence or absence of at least two variant nucleotides in a nucleic acid sample associated with thrombosis (see page 14, paragraph 1 under example section, 21, line 17-32) comprising

a) amplifying the sample regions of DNA that include at least two nucleotides positions for which variants are known to be associated with thrombosis to form amplified DNA products (see page 5, paragraph 3, page 6, line 1-2, page 14, paragraph 1 under example section page 21, line 17-32);

b) hybridizing at least two tagged (primers comprising non-complementary sequence at 3' terminus) allele specific primers complementary to target sequence in the amplified DNA products (see page 6, line 2-20, page 7, line 1-33);

c) extending the at least two tagged allele specific extension primers using labeled nucleotides, if the terminal nucleotide of each 3' end hybridizing portion is a perfect match to the corresponding amplified product (see page 6, line 21-24);

d) and detecting the presence of labeled extension products (see page 6, line 25-29).

However Reuber et al. did not teach tag sequences comprising terminal sequences of SEQ ID Nos. 2, 4, 13 or 14.

Pancoska et al. teach minimally cross-hybridizing nucleic acid tag sequences for detection of presence or absence of a mutation or polymorphism in a nucleic acid sample (see col. 4, line 18-46, table 1, col. 21, line 4-67).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method as taught by Reuber et al. with sequence tags as taught by Pancoska et al. to achieve expected advantage of developing an

improved sensitive method. An ordinary practitioner would have motivated to combine the method with the sequence tags of Pancoska et al. because the ordinary person skilled in the art would have a reasonable expectation of success that the combination would result in enhancing the sensitivity of the method because Pancoska et al. explicitly taught the significance of using minimally cross-hybridizing tag sequences in identifying mutations or polymorphisms in a sample nucleic acid (see col. 21, line 4-67) and such modification of the method is considered obvious over the cited prior art.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/  
Primary Examiner, Art Unit 1637

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